

**DOCKET NO.: 100051.10611**

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: **Scott A. Waldman**

Title: **METASTATIC COLORECTAL CANCER VACCINE**

Patent No.: **7,598,229**

Issued: **October 6, 2009**

Serial No.: **10/695,578**

Group Art Unit: **1642**

Examiner: **Sean E Aeder**

Confirmation No.: **5382**

Filed by EFS Web on: **October 30, 2009**

**Mail Stop Petition**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Dear Sir:

**REQUEST FOR CORRECTION OF PATENT TERM ADJUSTMENT**

**UNDER 37 C.F.R. § 1.705(d)**

Patentee hereby requests reconsideration of the Patent Term Adjustment (PTA) accorded the above-referenced patent. Reconsideration of the final PTA calculation to increase total PTA from 370 to 703 days, is respectfully requested.

**Remarks**

**Measuring Overlap of “A Delay” and “B Delay”**

“A Delays” are defined as delays by the U.S. Patent and Trademark Office (PTO) under 35 U.S.C. § 154(b)(1)(A), which guarantees prompt PTO response. “B Delays” are defined as delays by the PTO under 35 U.S.C. § 154(b)(1)(B), which guarantees no more than three year application pendency. To the extent that the periods of delay overlap, the period of any term adjustment shall not exceed the actual number of days the issuance of the patent was delayed. 35 U.S.C. § 154(b)(2)(A). As outlined in Wyeth et al. v. Jon W. Dudas (U.S. District Court, D.C., CA No. 07-1492, Mem. Op. September 30, 2008), the only way that these periods of time can

“overlap” is if they occur on the same day. If an “A delay” occurs on one calendar day and a “B delay” occurs on another calendar day, they do not overlap and 35 U.S.C. § 154(b)(2)(A) does not limit the extension to one day. Id.

The PTA for the instant patent, as currently calculated and shown on the face of the patent, apparently relies on the premise that the application was delayed under 35 U.S.C. § 154(b)(1)(B) *before* the initial three-year period expired. The Wyeth v. Dudas court determined that this construction cannot be squared with the language of 35 U.S.C. § 154(b)(1)(B), which applies “if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years.” “B delay” begins only after the PTO has failed to issue a patent within three years, not before. Id.

#### **REVIEW OF PATENT TERM ADJUSTMENT CALCULATION**

##### **“A Delay”**

A first PTO action was due on or before December 27, 2004 (the date that is fourteen months after October 27, 2003, the filing date of the above-referenced patent). The PTO mailed the first action (a restriction requirement) on June 26, 2006, thereby according a PTO Delay of 546 days. Patentee does not dispute the PTO’s calculation for this “A Delay” from December 28, 2004 (the day after the date that is fourteen months after the filing date of the above-referenced patent), to June 26, 2006. See 37 C.F.R. §§ 1.702(a)(1) and 1.703(a)(1).

In view of the period of “A Delay” detailed above, the total “A Delay” for this patent should be calculated as 546 days.

##### **“B Delay”**

Pursuant to Rule 37 C.F.R. § 1.703(b) and 35 U.S.C. § 154, the Office was to grant a term adjustment for the number of days that exceeds 3 years from the filing date of the application to the issue date of the application, excluding the period following the filing of an RCE, and the period of appeal. A Notice of Appeal was filed on October 7, 2007, which was followed by an RCE on May 2, 2008.

The above-referenced patent was filed on October 27, 2003. The period beginning on October 28, 2006 (the day after the date that is three years after October 27, 2003), and ending October 2, 2007, the date that a notice of appeal was filed, is 340 days in length.

In view of the period of “B Delay” detailed above, the total “B Delay” for this patent should be calculated as 340 days. The PTO calculated 7 days of delay for issuance of a patent more than three years after filing. Patentee respectfully submits that the PTO’s calculation of this “B Delay” is incorrect and that the correct PTO Delay for issuance beyond three years from filing is 340 days. See 37 C.F.R. §§ 1.702(b) and 1.703(b) and Wyeth.

**Overlap of “A Delay” and “B Delay”**

As detailed above, “A Delay” accumulated during the following period:

December 28, 2004, to June 26, 2006.

As detailed above, “B Delay” accumulated during the following period:

October 28, 2006, to October 2, 2007.

The “A Delay” and the “B Delay” did not overlap (See, Wyeth).

**Applicant Delay**

Applicant does not dispute the USPTO determination of 183 days of Applicant delay.

**Terminal Disclaimer**

This patent is not subject to a terminal disclaimer.

**Conclusion**

In consideration of the events described above, Patentee believes the PTA calculation of 370 days is incorrect. As such, Patentee respectfully requests reconsideration of the PTA in the following manner:

- 1) Total PTO Delay should be calculated as 886 days (i.e., the sum of 546 days of “A Delay” and 340 days of “B Delay” minus the 0 days of overlap);
- 2) Total Applicant Delay should be calculated as 183 days; and
- 3) **Total PTA should be calculated as 703 days.**

The Commissioner is hereby authorized to debit any fee due or credit any overpayment to deposit account 50-0436.

Respectfully submitted,

/Daniel M. Scolnick, Reg.# 52201/  
Daniel M. Scolnick, Ph.D.  
Registration No. 52,201

Date: October 30, 2009

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Respectfully submitted,

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10/695,578 METASTATIC COLORECTAL CANCER VACCINE

10-29-  
2009::17:35:08**Patent Term Adjustments**

Patent Term Adjustment (PTA) for Application Number: 10/695,578

Filing or 371(c) Date:	10-27-2003	USPTO Delay (PTO) Delay (days):	553
Issue Date of Patent:	10-06-2009	Three Years:	-
Pre-Issue Petitions (days):	+0	Applicant Delay (APPL) Delay (days):	183
Post-Issue Petitions (days):	+0	Total PTA (days):	370
USPTO Adjustment(days):	+0	Explanation Of Calculations	

**Patent Term Adjustment History**

Date	Contents Description	PTO(Days)	APPL(Days)
09-16-2009	PTA 36 Months	7	
10-06-2009	Patent Issue Date Used in PTA Calculation		
09-02-2009	Dispatch to FDC	↑	
09-02-2009	Application Is Considered Ready for Issue	↑	
08-28-2009	Issue Fee Payment Verified	↑	
08-28-2009	Issue Fee Payment Received	↑	
06-16-2009	Sequence Forwarded to Pubs on Tape	↑	
06-03-2009	Mail Notice of Allowance	↑	
06-02-2009	Document Verification	↑	
06-02-2009	Notice of Allowance Data Verification Completed	↑	
05-28-2009	Examiner's Amendment Communication	↑	
04-21-2009	Date Forwarded to Examiner	↑	
04-13-2009	Amendment after Final Rejection		1
03-20-2009	Mail Advisory Action (PTOL - 303)		↑
03-18-2009	Advisory Action (PTOL-303)		↑
02-24-2009	Date Forwarded to Examiner		↑
02-12-2009	Amendment after Final Rejection		↑
01-12-2009	Mail Final Rejection (PTOL - 326)		↑
01-09-2009	Final Rejection		
11-17-2008	Date Forwarded to Examiner		
11-11-2008	Supplemental Response		1
11-17-2008	Date Forwarded to Examiner		↑
11-10-2008	Response after Non-Final Action		31
11-10-2008	Request for Extension of Time - Granted		↑
07-10-2008	Mail Non-Final Rejection		↑
07-07-2008	Non-Final Rejection		
05-05-2008	Affidavit(s) (Rule 131 or 132) or Exhibit(s) Received		
05-05-2008	Miscellaneous Incoming Letter		
05-02-2008	Affidavit(s) (Rule 131 or 132) or Exhibit(s) Received		
05-02-2008	Affidavit(s) (Rule 131 or 132) or Exhibit(s) Received		
05-07-2008	Date Forwarded to Examiner		

05-07-2008	Date Forwarded to Examiner	
05-02-2008	Request for Continued Examination (RCE)	
05-07-2008	DISPOSAL FOR A RCE/CPA/129 (express abandonment if CPA)	
05-02-2008	Request for Extension of Time - Granted	
05-02-2008	Workflow - Request for RCE - Begin	
10-02-2007	Notice of Appeal Filed	61
10-02-2007	Request for Extension of Time - Granted	↑
05-02-2007	Mail Final Rejection (PTOL - 326)	↑
04-30-2007	Final Rejection	
02-27-2007	Affidavit(s) (Rule 131 or 132) or Exhibit(s) Received	
03-04-2007	Date Forwarded to Examiner	
02-27-2007	Response after Non-Final Action	89
02-27-2007	Request for Extension of Time - Granted	↑
08-31-2006	Mail Non-Final Rejection	↑
08-29-2006	Non-Final Rejection	
05-04-2005	Information Disclosure Statement considered	
07-28-2006	Correspondence Address Change	
07-31-2006	Change in Power of Attorney (May Include Associate POA)	
07-28-2006	Date Forwarded to Examiner	
07-26-2006	Response to Election / Restriction Filed	
06-26-2006	Mail Restriction Requirement	546
06-22-2006	Requirement for Restriction / Election	↑
06-06-2006	Case Docketed to Examiner in GAU	↑
04-24-2006	Case Docketed to Examiner in GAU	↑
09-13-2005	Case Docketed to Examiner in GAU	↑
05-04-2005	Reference capture on IDS	↑
05-04-2005	Information Disclosure Statement (IDS) Filed	↑
05-04-2005	Information Disclosure Statement (IDS) Filed	↑
05-11-2005	Transfer Inquiry to GAU	↑
03-30-2005	Case Docketed to Examiner in GAU	↑
04-23-2004	IFW TSS Processing by Tech Center Complete	↑
04-23-2004	Case Docketed to Examiner in GAU	↑
04-14-2004	Application Return from OIPE	↑
04-15-2004	Application Is Now Complete	↑
04-14-2004	Application Return TO OIPE	↑
04-14-2004	Application Return from OIPE	↑
04-14-2004	Application Return TO OIPE	↑
04-14-2004	Application Return from OIPE	↑
04-14-2004	Application Is Now Complete	↑
04-14-2004	Application Return TO OIPE	↑
04-14-2004	Application Return from OIPE	↑

04-14-2004	Application Is Now Complete	↑
04-06-2004	CRF Is Good Technically / Entered into Database	↑
10-27-2003	CRF Disk Has Been Received by Preexam / Group / PCT	↑
03-12-2004	Pre-Exam Office Action Withdrawn	↑
03-12-2004	Application Return TO OIPE	↑
03-11-2004	Application Dispatched from OIPE	↑
03-11-2004	Application Is Now Complete	↑
01-28-2004	Cleared by L&R (LARS)	↑
01-20-2004	Referred to Level 2 (LARS) by OIPE CSR	↑
12-02-2003	IFW Scan & PACR Auto Security Review	↑
10-27-2003	Initial Exam Team nn	↑

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